DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 25, 2014

Vascular Solutions, Inc.
Ellie Gillespie
Sr. Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, MN 55369

Re: K142065
Trade/Device Name: Turnpike Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 30, 2014
Received: October 31, 2014

Dear Ms. Ellie Gillespie,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142065

Device Name: Turnpike catheter

Indications for Use:

Turnpike catheter is intended to be used to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and to subselectively infuse/deliver diagnostic and therapeutic agents.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: August 15, 2014

510(k) Number: K142065

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court North
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Ellie Gillespie
Sr. Regulatory Product Specialist
Tel: 763-656-4300
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General Information

Trade Name	Turnpike catheter
Common / Usual Name	catheter
Classification Name	870.1250, DQY - Percutaneous catheter, Class II
Predicate Device(s)	K091345 - Gopher Gold catheter (Vascular Solutions, Inc.) K051772 - Tornus Support Catheter (Asahi Intecc Co., Ltd.)

Device Description

The Turnpike catheter is a single lumen catheter designed for use in the coronary and/or peripheral vasculature. The shaft is constructed of two polymer layers that encapsulate a braid and a dual-layer coil. Turnpike has a radiopaque tip (polymer or gold-plated) and is available in various tip and shaft configurations and one of three working lengths. Turnpike catheter is hydrophilic coated and is compatible with 0.014" guidewires and 5F guide catheters.

Intended Use / Indications

Turnpike catheter is intended to be used to access discrete regions of the coronary and/or peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and to subselectively infuse/deliver diagnostic and therapeutic agents.

Technological Characteristics Comparison

Turnpike catheter is similar in design and intended use to the predicate devices as they are all single lumen, percutaneous catheters intended to access discrete regions of the coronary and peripheral vasculature and for 0.014" guidewire exchange. The subject and predicate devices are similar in size (approximately 3F) and compatible with 5F guide catheters. Turnpike catheter is available in longer working lengths than the predicate devices. The subject device has an external polymer shaft coil and tip threads that are similar in intended function but smaller in height than comparable features on the predicate devices. Turnpike catheter has a hydrophilic coat for smooth introduction. The types of materials used in the subject device and one of the predicate devices are similar but vary slightly.

Substantial Equivalence and Summary of Studies

Technological differences between the subject and predicate devices have been evaluated through biocompatibility and mechanical tests to provide evidence that Turnpike catheter is as safe and effective as the predicate devices. Turnpike catheter is substantially equivalent to the specified predicate devices based on comparisons of device functionality, technological characteristics, and indications for use. The subject device design has been verified and validated through the following mechanical tests:

- Working length
- Tip and shaft thread functionality
- Radiopacity
- Hydrophilic coating particulate
- Hydrophilic coating delamination
- Tortuosity, guide catheter profile, guidewire passage
- Torque

The following biocompatibility tests were performed as recommended by ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis
- Complement Activation
- In Vitro Hemocompatibility
- Coagulation
- Thrombogenicity

Verification and validation test results met the specified acceptance criteria and did not raise new questions of safety or effectiveness issues. Therefore, Turnpike catheter is substantially equivalent to the predicate devices.